CLAIMS:

1. An implantable medical device having a connector header adapted to be coupled through the use of a tool to an electrical lead connector element of an elongated electrical medical lead, wherein:

the connector header is formed of a header body having at least one header connector bore and a header grommet aperture having a grommet aperture sidewall;

a connector block is disposed within the connector header having a threaded bore aligned with the header grommet aperture and a connector block bore aligned with the header connector bore adapted to receive a lead connector element when a proximal connector assembly of the elongated electrical medical lead is received in the header connector bore;

a setscrew is threaded into the threaded bore having a setscrew socket disposed to be engaged by the tool to enable rotation of the setscrew within the threaded bore to tighten the setscrew against or to loosen the setscrew from a lead connector element received in the header connector bore;

a penetrable grommet is disposed within the header grommet aperture, the penetrable grommet comprising a generally cylindrical elastomer body having a grommet central axis and including a self-sealing passage extending between opposed grommet inner and outer end walls enabling passage of the tool therethrough into the setscrew socket for rotating the setscrew and sealing of the passage upon withdrawal of the tool; and

a ring-shaped retainer having a central bore aligned with the grommet central axis that the tool can be passed through is disposed against an annular portion of the outer end wall, the ring-shaped retainer affixed to a portion of the header body surrounding the header grommet aperture, whereby the penetrable grommet is retained within the header grommet aperture.

2. The implantable medical device of Claim 1, wherein the self sealing passage comprises a slit extending between the outer and inner end walls of the disc-shaped penetrable grommet and aligned to the grommet central axis and within the central bore, whereby the ring-shaped retainer guides precise alignment and insertion of the tool through the slit into operative engagement with the setscrew.

3. The implantable medical device of Claim 2, wherein:

the header body is formed of a material of a first color, and

the ring-shaped retainer is formed of a material of a second color contrasting from the first color and providing a visible target for precisely aligning and inserting the tool through the central bore and the slit into operative engagement with the setscrew.

4. The implantable medical device of Claim 3, wherein the header body and the ring-shaped retainer are formed of thermoplastic materials, and the ring-shaped retainer is thermally bonded to a portion of the header body surrounding the header grommet aperture.

5. The implantable medical device of Claim 4, wherein the penetrable grommet disposed within the header grommet aperture is formed of a compound of silicone rubber filled with an additive decreasing the tendency of slit healing of the slit over time and facilitating passage of the tool therethrough into the setscrew socket for rotating the setscrew and sealing of the passage upon withdrawal of the tool.

6. The implantable medical device of Claim 5, wherein the penetrable grommet disposed within the header grommet aperture is formed of a compound of silicone rubber compounded with titanium dioxide in a concentration of up to about two percent by weight.

7. The implantable medical device of Claim 5, wherein the additive renders the compound opaque in color contrasting from the first and second colors.

8. The implantable medical device of Claim 7, wherein the penetrable grommet disposed within the header grommet aperture is formed of a compound of silicone rubber compounded with titanium dioxide in a concentration of up to about two percent by weight.

9. The implantable medical device of Claim 2, wherein the header body and the ring-shaped retainer are formed of a thermoplastic material, and the ring-shaped retainer is thermally bonded to a portion of the header body surrounding the header grommet aperture.

10. The implantable medical device of Claim 9, wherein the penetrable grommet disposed within the header grommet aperture is formed of a compound of silicone rubber filled with an additive decreasing the tendency of slit healing over time and facilitating passage of the tool therethrough into the setscrew socket for rotating the setscrew and sealing of the passage upon withdrawal of the tool.

11. The implantable medical device of Claim 10, wherein the penetrable grommet disposed within the header grommet aperture is formed of a compound of silicone rubber compounded with titanium dioxide in a concentration of up to about two percent by weight.

12. The implantable medical device of Claim 10, wherein:

the header body is formed of a material of a first color, and

the additive colors the compound in a color contrasting from the first color providing a visible target for precisely aligning and inserting the tool through the central bore and the slit into operative engagement with the setscrew.

13. The implantable medical device of Claim 12, wherein the penetrable grommet disposed within the header grommet aperture is formed of a compound of silicone rubber compounded with titanium dioxide in a concentration of up to about two percent by weight.

14. The implantable medical device of Claim 2, wherein the penetrable grommet disposed within the header grommet aperture is formed of a compound of silicone rubber filled with an additive decreasing the tendency of slit healing over time and facilitating passage of the tool therethrough into the setscrew socket for rotating the setscrew and sealing of the passage upon withdrawal of the tool.

15. The implantable medical device of Claim 14, wherein the penetrable grommet disposed within the header grommet aperture is formed of a compound of silicone rubber compounded with titanium dioxide in a concentration of up to about two percent by weight.

16. The implantable medical device of Claim 14, wherein:

the header body is formed of a material of a first color, and

the additive colors the compound in a color contrasting from the first color providing a visible target for precisely aligning and inserting the tool through the central bore and the slit into operative engagement with the setscrew.

17. The implantable medical device of Claim 16, wherein the penetrable grommet disposed within the header grommet aperture is formed of a compound of silicone rubber compounded with titanium dioxide in a concentration of up to about two percent by weight.

18. The implantable medical device of Claim 2, wherein the generally cylindrical elastomer body of the penetrable grommet includes a grommet sidewall extending between the opposed inner and outer end walls, the grommet sidewall formed having an irregular surface comprising a plurality of peaks and valleys that maintains fluid sealing contact with the cylindrical sidewall of the tubular header grommet aperture without adhesive therebetween.

19. The implantable medical device of Claim 18, wherein the grommet aperture has a nominal inner diameter and the grommet sidewall is formed having a nominal peak-to-peak outer diameter exceeding the nominal inner diameter of the sidewall to provide a low pressure interference fit upon insertion of the penetrable grommet into the header grommet aperture, whereby a low, uniform, interference pressure is attained over a wide tolerance upon assembly that is maintained even if the inner diameter of the cylindrical sidewall of the tubular header grommet aperture changes over extended time periods.

20. The implantable medical device of Claim 19, wherein the grommet aperture has a nominal inner diameter and the grommet sidewall is formed having a plurality of sealing rings having nominal sealing ring outer diameters exceeding the nominal inner diameter of the sidewall to provide a low pressure interference fit upon insertion of the penetrable grommet into the header grommet aperture, whereby a low, uniform, interference pressure is attained over a wide tolerance upon assembly that is maintained even if the inner diameter of the cylindrical sidewall of the tubular header grommet aperture changes over extended time periods.

21. The implantable medical device of Claim 2, wherein a yield space is provided between the inner end wall of the grommet and the setscrew socket to accommodate the elastomer body of the grommet that is pushed inward by the tool advanced through the slit.

22. The implantable medical device of Claim 28, wherein the yield space is provided at least in part by a recess extending into the inner end wall of the penetrable grommet.

23. The implantable medical device of Claim 1, wherein:

the threaded bore of the connector block has a spiral bore thread of a bore thread diameter; and

the setscrew comprises a setscrew body having a spiral setscrew thread dimensioned to be received by the spiral bore thread and a setscrew socket head having a socket head diameter greater than the bore thread diameter.

24. The implantable medical device of Claim 23, wherein the setscrew socket head comprises a ring formed of a plastic material molded around a portion of the spiral setscrew thread.

25. The implantable medical device of Claim 23, wherein the setscrew socket head is enlarged in diameter surrounding the setscrew socket providing a funnel-shaped opening to the setscrew socket to ease insertion of the tool through the pre-formed slit and into the setscrew socket.

26. The implantable medical device of Claim 1, wherein the setscrew has a setscrew socket in a setscrew body extending between a setscrew socket head and a setscrew working end is disposed between the penetrable grommet and the connector block, the setscrew body having a spiral setscrew thread mating with the spiral bore thread of the threaded bore, and the setscrew socket

head having a socket head diameter exceeding the bore thread diameter, whereby the setscrew socket head is adapted to be engaged by the tool inserted through the penetrable grommet to enable rotation of the setscrew body within the threaded bore to tighten the setscrew working end against or to loosen the setscrew working end from a lead connector element received in the connector block bore, and the socket head diameter inhibits advancement of the setscrew all of the way through the threaded bore.

27. The implantable medical device of Claim 26, wherein the setscrew is rotatable by a setscrew tool inserted through the penetrable grommet into the setscrew socket until the enlarged diameter setscrew socket end is retracted into frictional engagement with the penetrable grommet, whereby the frictional engagement stabilizes the setscrew in the retracted position and inhibits spontaneous migration of the setscrew body through the threaded bore disposing the setscrew working end in the connector block bore.

28. The implantable medical device of Claim 27, wherein the header body is formed having a setscrew retention space between the connector block and the penetrable grommet receiving the setscrew body when the enlarged diameter setscrew socket end is retracted into frictional engagement with the inner end wall of the penetrable grommet.

29. The implantable medical device of Claim 28, wherein the setscrew socket head surrounding the setscrew socket is formed with a funnel-shaped opening without a sharp cutting edge that guides a setscrew tool end into the setscrew socket and provides a space accommodating any elastomer material of the penetrable grommet displaced by the setscrew tool.

30. The implantable medical device of Claim 26, wherein the setscrew socket head comprises a ring of a plastic material molded around a portion of the setscrew body.

31. The implantable medical device of Claim 26, wherein the setscrew socket extends for substantially the full length of the setscrew body from the setscrew socket head to the setscrew working end to maximize setscrew socket depth and mutual contact area of the setscrew and the setscrew tool.

32. An implantable medical device having a connector header adapted to be coupled through the use of a tool to an electrical lead connector element of an elongated electrical medical lead, wherein:

the connector header is formed of a header body having at least one header connector bore, a header grommet aperture having a grommet aperture sidewall, and a retention groove extending into the header body spaced away from and substantially surrounding the header grommet aperture sidewall;

a connector block is disposed within the connector header having a threaded bore aligned with the header grommet aperture and a connector block bore aligned with the header connector bore adapted to receive a lead connector element when a proximal connector assembly of the elongated electrical medical lead is received in the header connector bore;

a setscrew is threaded into the threaded bore having a setscrew socket disposed to be engaged by the tool to enable rotation of the setscrew within the threaded bore to tighten the setscrew against or to loosen the setscrew from a lead connector element received in the header connector bore;

a penetrable grommet is disposed within the header grommet aperture, the penetrable grommet comprising a generally cylindrical elastomer body having a grommet central axis and including a self-sealing passage extending between opposed inner and outer end walls enabling passage of the tool therethrough into

the setscrew socket for rotating the setscrew and sealing of the passage upon withdrawal of the tool; and

a retainer cap having a central cap opening aligned with the grommet central axis that the tool can be passed through is disposed against an annular portion of the outer end wall, and a cap sidewall is fitted into the retention groove to entrap the penetrable grommet within the grommet aperture.

33. The implantable medical device of Claim 32, wherein the retainer cap is formed of a rigid material, whereby the cap sidewall fitted into the retention groove stabilizes a portion of the header body between the retention groove and the grommet aperture sidewall from changing substantially in dimension over chronic implantation time.

34. The implantable medical device of Claim 32, wherein the retainer cap sidewall is formed with at least one retention flange extending laterally that engages the header body upon insertion of the cap sidewall into the groove and resist removal of the ring-shaped cap.

35. The implantable medical device of Claim 32, wherein the cap sidewall is further formed with enhancements for promoting adhesion with the header body upon application of thermal energy to the thermoplastic material of the header body contacting the enhancements.

36. The Implantable medical device of Claim 35, wherein the enhancements comprise at least one aperture through the cap sidewall into which thermoplastic material flows upon melting through application of thermal energy and solidifies upon cooling of the thermoplastic material.

37. The implantable medical device of Claim 36, wherein each aperture comprises a notch in the cap sidewall with a key slot that receives a key of thermoplastic material formed within the retention groove inserted into the key slot and filling the notch.